

FINDING OF NO SIGNIFICANT IMPACT

for

IVOMEC® (Ivermectin)
1% Injection in Swine

NADA 135-008

Merck Sharp & Dohme Research Labs
Rahway, NJ

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Merck Sharp & Dohme Research Labs has requested approval of a supplement to NADA 135-008 to provide for the use of ivermectin in swine for the treatment and control of the somatic larval stages of the intestinal threadworm (Strongyloides ransomi). Pigs are to be dosed by subcutaneous injection at a level of 0.3 milligrams of drug per kilogram of pig body weight. This level of ivermectin use in swine is already approved for the treatment and control of the adult life stage of S. ransomi and different life stages of other nematode species (Federal Register of July 29, 1986; 51 FR 27020).

In support of the approval of the supplement, Merck Sharp and Dohme submitted an amended environmental assessment (EA) dated November 9, 1987 (copy attached). This EA states that the addition of the claim for the somatic larval stages of S. ransomi should not add significantly to the introduction of this drug into the environment. This is because most of the swine infected with the somatic larval stage of this parasite are already being treated with this drug, either for the adult parasite, or for other nematode parasites. The potential environmental impacts which could result from the already approved uses of ivermectin in swine was addressed in an EA dated June 30, 1985, which is appended to the EA dated November 9, 1987.

The Center has reviewed the EA for this action and has determined that it provides sufficient information to support a conclusion that the proposed use of ivermectin for the treatment and control of somatic larval stages of S. ransomi in swine would not be expected to cause significant environmental impacts.

2-12-88
Date

M. Zeman
Preparer, HFV-162

Date

Primary Action Officer, HFV-135

2-12-88
Date

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Attachment